UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,837	12/07/2005	Soojin Lee	CMT-0016	2897

23413 7590 04/14/2008

CANTOR COLBURN, LLP
20 Church Street
22nd Floor
Hartford, CT 06103

EXAMINER	
NGUYEN, QUANG	
ART UNIT	PAPER NUMBER
1633	

MAIL DATE	DELIVERY MODE
04/14/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/530,837	LEE ET AL.	
	Examiner	Art Unit	
	QUANG NGUYEN, Ph.D.	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 January 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) *12-36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 5-11* is/are rejected.

7)☒ Claim(s) *2-4* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 April 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/18/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-36 are pending in the present application.

Applicant's election with traverse of Group I (claims 1-11) and SEQ ID NO:1 in the reply filed on 1/22/08 is acknowledged. The traversal is on the ground(s) that an isolated nucleic acid molecule comprising SEQ ID NO:1 and an isolated nucleic acid molecule encoding SEQ ID NO:2 provide different definitions of the same disclosed invention and that search and examination of both SEQ ID NO:1 and SEQ ID NO:2 would not create a serious burden for the examiner. Additionally, Applicant argues that SEQ ID NOS: 1-4 all share a technical relationship linking them to form a single general inventive concept because LGF1 is encoded by both SEQ ID NOS: 1 and 3, and that the protein sequence of SEQ ID NO:2 is identical to that of SEQ ID NO:4 except that SEQ ID NO:2 lacks the first 134 amino acids at the N-terminus of SEQ ID NO:4. Applicant further argues that claims 12-13 of Group II with respect to SEQ ID NOS:2 and 4, should be examined with and not restricted from the claims of Group I because they have unity of invention.

Upon further consideration, the examiner will examine claims drawn to an isolated nucleic acid molecule comprising SEQ ID NO:1, an isolated nucleic acid molecule comprising SEQ ID NO:3 as well as isolated nucleic acid molecules encoding SEQ ID NO:2 and SEQ ID NO:4, a vector, a host cell comprising the same and a method for producing a polypeptide using the same. Therefore, most of Applicant's above arguments are moot. With respect to Applicant's request for rejoining claims 12-13 of Group II together with claims of Group I, an isolated nucleic acid molecule of

Group I and an isolated polypeptide of Group II are different structurally and chemically one from the other. For example, at least an isolated nucleic acid molecule of Group I is composed of nucleotides while an isolated polypeptide of Group II is made up of amino acid residues; and therefore they lack the same or corresponding special technical feature.

It is also noted that Applicants did not traverse the restriction with respect to other Groups (Groups III-XI) as set forth in the Office action mailed on 12/26/07 (pages 2-8).

The requirement is still deemed proper and is therefore made FINAL.

Accordingly, claims 12-36 are withdrawn from further consideration because they are directed to non-elected inventions.

Claims 1-11 are examined on the merits herein with respect to an isolated nucleic acid molecule comprising SEQ ID NO:1, an isolated nucleic acid molecule comprising SEQ ID NO:3 as well as isolated nucleic acid molecules encoding SEQ ID NO:2 and SEQ ID NO:4, a vector, a host cell comprising the same and a first method of use for producing a polypeptide using the same.

Priority

The present application is a 371 of PCT/KR03/02161, filed on 10/16/2003, which claims benefit of 60/419,911, filed on 10/18/2002; 60/419,912, filed on 10/18/2002; 60/420,088, filed on 10/18/2002; 60/434,243, filed on 12/16/2002; 60/434,278, filed on 12/16/2002; and 60/438,278, filed on 01/03/2003.

Upon review of the specifications of the above provisional applications and comparison with the specification of the present application, it is determined that with respect to the elected invention claims 1-11 are only entitled **at best to the effective filing date of 12/16/2002** because SEQ ID NOs. 1-4 were first disclosed in the specification of the provisional application 60/434,278.

Claim Objections

Claims 1-11 are objected to because they contain embodiments directed to non-elected inventions (e.g., SEQ ID NOs. 5-16). Appropriate correction is required.

Written Description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 5-11 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111 (Fed. Cir. 1991), clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for

purposes of the 'written description' inquiry, *whatever is now claimed.*" Vas-Cath Inc. v. Mahurkar, 19USPQ2d at 1117. The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." Vas-Cath Inc. v. Mahurkar, 19USPQ2d at 1116.

With respect to the elected invention, an embodiment of the instant broadly claimed invention is drawn to an isolated nucleic acid molecule that encodes a protein that is expressed in cancer and that exhibits at least about 75% nucleotide sequence identity over the entire contiguous sequence of SEQ ID NOs. 1 and 3 as well as its complement; a vector and a host cell comprising the same isolated nucleic acid molecule and a method for producing a polypeptide comprising culturing the same recombinant host cell.

Apart from disclosing SEQ ID NO:1 (encoding SEQ ID NO:2) and SEQ ID NO:3 (encoding SEQ ID NO:4) which are significantly upregulated in cancer tissue samples compared to samples from corresponding normal tissues , the instant speciation fails to provide any description for **other nucleic acid molecules that are expressed in cancer and that exhibit at least about 75% nucleotide sequence identity over the entire contiguous sequence of SEQ ID NO:1 and/or SEQ ID NO:4, encompassing nucleic acid molecules containing naturally occurring allelic variants and mutations (insertions, deletions, substitutions)**. For examples, what are the detailed essential **characteristics or elements possessed by** these other nucleic acid molecules as broadly claimed? The instant disclosure does not reasonably convey to a skilled artisan at the time the invention was made that **Applicant was in possession of**

a representative number of species for a broad genus of an isolated nucleic acid molecule that encodes a protein that is expressed in cancer and that exhibits at least about 75% nucleotide sequence identity over the entire contiguous sequence of SEQ ID NOs. 1 and 3 as well as its complement; a vector and a host cell comprising the same as claimed.

The claimed invention as a whole is not adequately described if the claims require essential or critical elements that are not adequately described in the specification. Possession may be shown by actual reduction to practice, clear depiction of the invention in a detailed drawing, or by describing the invention with sufficient relevant identifying characteristics such that a person skilled in the art would recognize that the inventor had possession of the claimed invention. Pfaff v. Wells Electronics, Inc., 48 USPQ2d 1641, 1646 (1998). The skilled artisan cannot fully envision the detailed structure for a representative number of species for **a broad genus of an isolated nucleic acid molecule that encodes a protein that is expressed in cancer and that exhibits at least about 75% nucleotide sequence identity over the entire contiguous sequence of SEQ ID NOs. 1 and 3 as well as its complement; a vector and a host cell comprising the same isolated nucleic acid molecule** as claimed, and therefore conception is not achieved until reduction to practice has occurred. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating or characterizing it. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) and *Amgen Inc. v. Chugai*

Pharmaceutical Co. Ltd., 18 USPQ2d 1016 (Fed. Cir. 1991). One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481, 1483.

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1 and 5-8 are rejected under 35 U.S.C. 102(e) as being anticipated by Venter et al. (WO 02/068579).

Venter et al already disclosed a human transcript sequence comprising SEQ ID NO: 2062 that is 72.4 % (about 75% nucleotide sequence identity) to the entire SEQ ID NO:1 or 73.7% to the entire SEQ ID NO: 3 of the present invention (see at least SEQ ID NO: 2062; page 3, first two full paragraphs; Summary of the Invention; page 14, first full paragraph). Venter et al further taught that the disclosed human coding sequences will be of great value for a variety of commercial purposes, including the production of encoded proteins and the development of therapeutic proteins and protein targets for

human intervention typically involves identifying a protein that can serve as a target for the development of a small molecule modulator (see at last page 10, lines 18-30). The isolated nucleic acid molecule can be fused to other coding or regulatory sequences or contained in a vector or be maintained in heterologous host cells (page 17, line 27 continues to line 10 of page 18).

Accordingly, the teachings of Venter et al meet at least an embodiment (c) of the instant broad claims. Therefore, the reference anticipates the instant claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 6 and 8-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Venter et al. (WO 02/068579) in view of Kuo et al. (EP 0150735).

Venter et al already disclosed a human transcript sequence comprising SEQ ID NO: 2062 that is 72.4 % (about 75% nucleotide sequence identity) to the entire SEQ ID NO:1 or 73.7% to the entire SEQ ID NO: 3 of the present invention (see at least SEQ ID NO: 2062; page 3, first two full paragraphs; Summary of the Invention; page 14, first full paragraph). Venter et al further taught that the disclosed human coding sequences will be of great value for a variety of commercial purposes, including the production of encoded proteins and the development of therapeutic proteins and protein targets for human intervention typically involves identifying a protein that can serve as a target for the development of a small molecule modulator (see at last page 10, lines 18-30). The isolated nucleic acid molecule can be fused to other coding or regulatory sequences or contained in a vector or be maintained in heterologous host cells (page 17, line 27 continues to line 10 of page 18).

Venter et al do not teach specifically the use of either prokaryotic or eukaryotic host cells comprising SEQ ID NO: 2062 or a method for producing a polypeptide comprising culturing a host cell transformed with SEQ ID NO: 2062, even though the reference discloses explicitly that the disclosed human coding sequence will be of great value for a variety of commercial purposes including the production of the encoded protein.

However, at the effective filing date of the present application Kuo et al already disclosed at least a method for the production of a heterologous protein, namely human

Factor VIIIC, precursors and subunits thereof, by expression in a microorganism such as *E. Coli*; *B. subtilis* or a mammalian tissue culture cell such as COS cells, CV-1 cells (see at least Summary of the Invention on page 2; page 13, lines 6-17; page 15, lines 6-19).

Accordingly, it would have been obvious for an ordinary skilled artisan to modify the teachings of Venter et al by also utilizing a prokaryotic host cell or a eukaryotic host cell for expressing a protein encoded by the human transcript comprising SEQ ID NO:2062 in light of the teachings of Kuo et al.

An ordinary skilled artisan would have been motivated to carry out the above modification because a recombinant protein expression utilizing either a prokaryotic or a eukaryotic host cell is well known and well established in the prior art as shown at least by the teachings of Kuo et al which taught successfully the expression of human Factor VIIIC, precursors and subunits thereof in a microorganism or a mammalian tissue culture cell.

An ordinary skilled artisan would have a reasonable expectation of success in light of the teachings of Venter et al., Kuo et al., coupled with a high level of skill of an ordinary skilled artisan in the relevant art.

Therefore, the claimed invention as a whole was *prima facie* obvious in the absence of evidence to the contrary.

Conclusions

No claim is allowed.

Claims 2-4 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang Nguyen, Ph.D., whose telephone number is (571) 272-0776.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's SPE, Joseph T. Woitach, Ph.D., may be reached at (571) 272-0739.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1633; Central Fax No. (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

/QUANG NGUYEN, Ph.D./
Primary Examiner, Art Unit 1633